GEA LYOPLUS™

Process Analytical Technology (PAT)
for Lyophilization

engineering for
a better world

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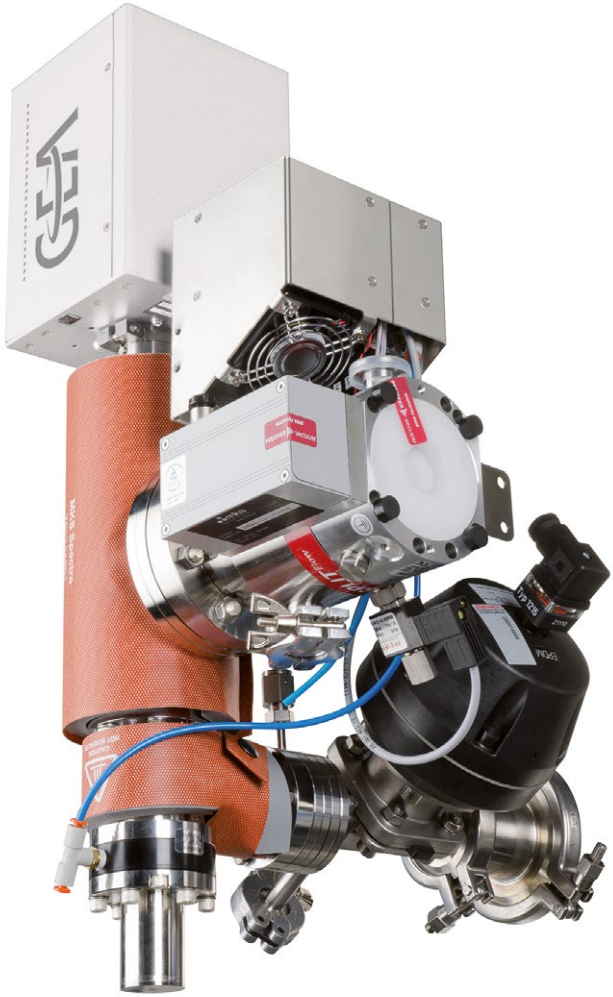
Improve your freeze drying

The GEA LYOPLUS™ mass spectrometer improves the safety, quality and productivity of freeze drying applications. Being able to prevent product contamination by detecting trace concentrations of silicone oil, the multipurpose device can also be used to monitor the moisture content in the product chamber during freeze drying cycles. As a result of exact monitoring, recipe-dependent moisture profiles can be derived, making it possible to define endpoints for primary and secondary drying. Furthermore the system can be used for efficient chamber leak detection.

A mobile GEA LYOPLUS™ solution can be rented for either test measurements or support for freeze dryer maintenance procedures such as leak check or shelves package exchange.

Benefits at a glance

- Detection of impurities possible before problems arise
- Providing valuable information for recipe development, scale-up and product transfers
- Fully automated system for use in pharmaceutical production environment with interfaces to existing freeze dryer automation
- Integrated interlocks and fault procedures to ensure sterility and machine availability
- Easy to retrofit (also on other brands of freeze dryers)



GEA LYOPLUS™ specifications

System details

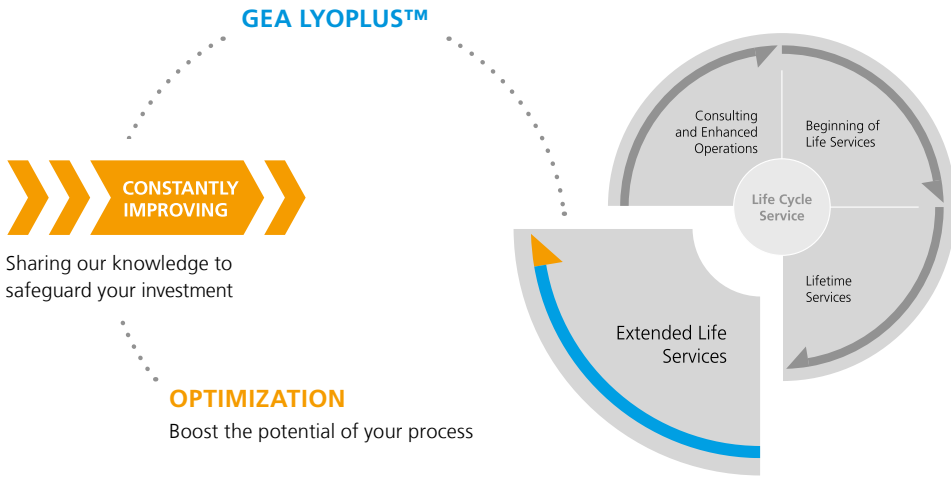
- High-performance quadrupole mass spectrometer system with Faraday and Secondary Electron Multiplier detectors
- Detection limit down to 1 ppm of non-interfering species
- High-conductance inlet system
- Tri-clamp connection by default or customer demand (<3 d)
- GEA LYOPLUS™ SCADA application compliant to 21 CFR Part 11 with User log, Audit trail and Batch reports
- Alarms & messages, e.g. for high silicone oil concentration
- Multilingual graphical user interface
- Various interfaces and functions to forward or export data
- Additional advanced data collection and control software for maintenance and diagnostic purposes
- Technical design and support documents
- System validation executed with IQ / OQ documentation and test procedures for proof of detectability (Spike Test)
- Training for operators and engineering staff

GEA LYOPLUS™ configurations

- Definition of possible configurations by aspects of mobility and software integration
- Aggregation of up to three GEA LYOPLUS™ systems in a single SCADA system
- Integration into existing automation environment according to customer demand incl. forwarding of alarms, feedbacks and measurement values

		Software integration				
		Stand-alone system				Integration into GEA FD SCADA
		Laptop	Desktop	Server	VM	
Mobility	Mobile solution	Standard	–	–	–	–
	Permanent installation	–	Standard	Option	Option	Yes

GEA Service – Four stages of continued success

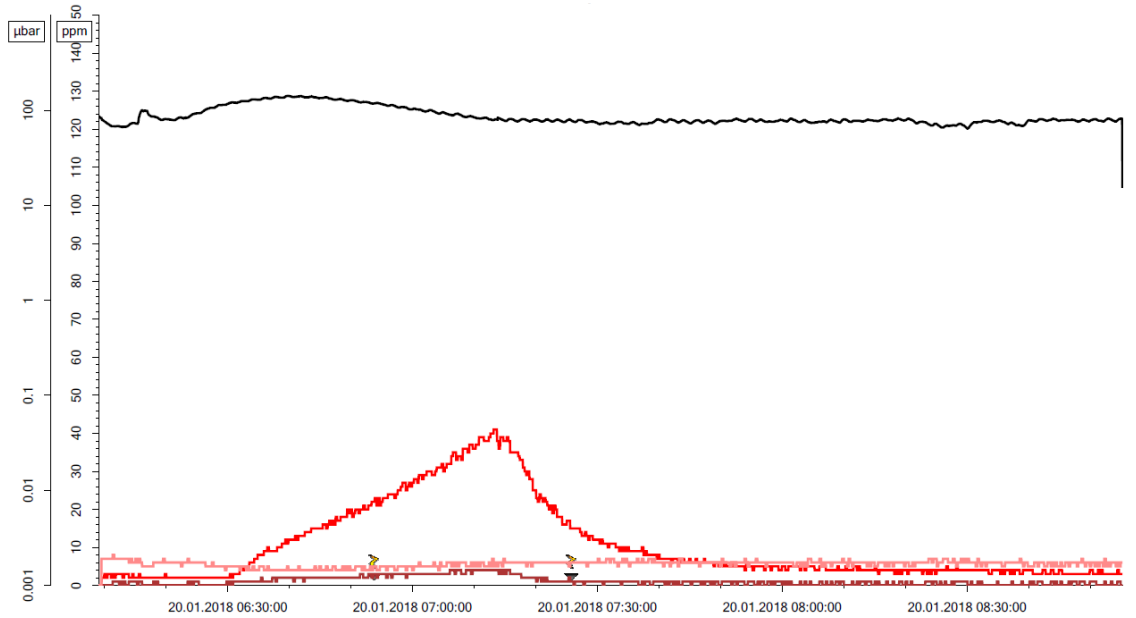


Silicone oil detection

When small leaks occur on the freeze dryer's shelves package, the silicone oil that is used as heat transfer medium can contaminate the product.

GEA LYOPLUS™ is able to detect very small traces of silicone oil during the operating cycle, facilitating the identification of a contaminated batch – prior to final quality testing – and ensuring that no additional product is put at risk.

Silicone oil detection – Trend diagram



Name	Style
Silicone Oil 71 ppm	
Silicone Oil 73 ppm	
Silicone Oil 75 ppm	
Total pressure PIRSA1.40	

Trend diagram from a silicone oil spike test showing the critical masses 71, 73 and 75 for silicone oils and the significant response on mass 73 (red).

Further GEA LYOPLUS™ services:

Training

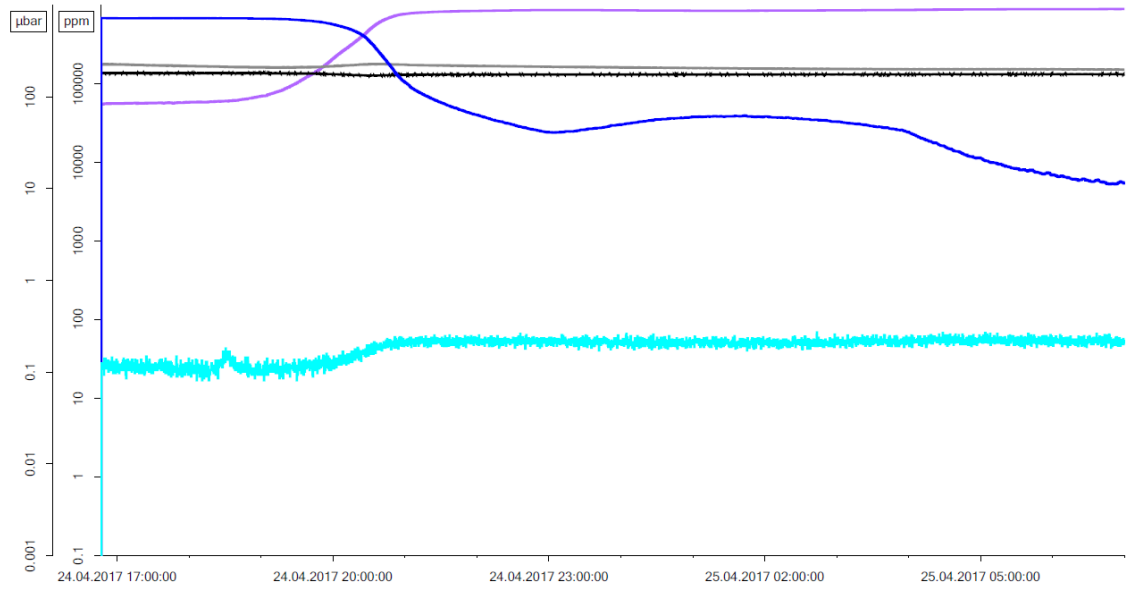
Spare parts packages (OEM)

Moisture content

During the freeze drying process, GEA LYOPLUS™ measures the decreasing amount of product-derived vapor in the product chamber.

Correlated with average product moisture levels, this data can be used to refine recipes, optimize processing times and predict product drying curves.

Moisture monitoring – Trend diagram



Name	Style
Argon ppm	
Nitrogen ppm	
Sum of partial pressures	
Total pressure PIRSA1.40	
Water ppm	

Trend diagram from a monitored freeze drying process showing the water vapor concentration (blue) in relation to the venting gas compound nitrogen (purple) and the process pressure (black/grey).

Annual preventive maintenance, incl. inspection, cleaning, calibration and documentation

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We live our values.

Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA is a global technology company with multi-billion euro sales operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA is listed in the STOXX® Europe 600 Index. In addition, the company is included in selected MSCI Global Sustainability Indexes.

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